K110888

ATTACHMENT II

510(K) SUMMARY (AS PER 21 CFR 807.92)

JAN 12 2012

I. GENERAL INFORMATION

Device Generic Name: Whitening Light

Trade Name: Absolute White Light

Device Classification: Heat Source for Bleaching Teeth
(21 CFR 872.6475)

Product Code: EEG

Applicant Name and Address:

Dr. Fresh, Inc.
6645 Caballero Blvd.
Buena Park, CA 90620

Contact Name: Gary Pendyala
714-690-1573

Date of Submission: December 15, 2011

510(k) Number: K110888

II. Device Description

The Absolute White Light is intended for use by the end consumer. The Absolute White Light is a battery operated, hand held device that contains a blue visible light in the 400 nanometer spectrum, which can penetrate the tooth and activate the photoactive substances within the tooth yielding a minimal amount of heat. Built in safety features include automatic light shut off after two minutes and "Light Guard" that prevents light exposure to the user's eyes.

III. Indications for Use

The Absolute White Light emits visible blue light in the 400 nanometer spectrum and is intended to provide a light source for bleaching teeth.

IV. Predicate Device

The Absolute White Light is substantially equivalent to other tooth whitening lights currently in commercial distribution such as the Dentovations, Inc. Luster Whitening System (formerly South Beach Smile Light and Klear Action) as cleared by the FDA under Accession Number K042153).

V. Summary of the Technical Characteristics of the Absolute White Light as Related to the Referenced Predicate Devices.

The Absolute White Light and the aforementioned predicate device are light sources for bleaching teeth as defined in 21 CFR 872.6475.

The Absolute White Light is a conventional tooth whitening light which works in conjunction with a bleaching agent to provide a light source for bleaching teeth. The Absolute White Light has the same intended use and similar technological characteristics to the predicate device.

Product	Absolute White Light	Dentovations Luster Light
Intended Use	*Light source Teeth Bleaching*	*Light source Teeth Bleaching*
Method of Use	*Hand Held*	*Hand Held*
Treatment Time	*2 minutes*	*2 minutes*
Treatment(s)	*As Needed*	*As Needed*
Area of Use	*Oral Cavity*	*Oral Cavity*
Light Source	*LED*	*LED*
Wavelength of Light	*400 nm*	*350 – 700 nm*
Color of Light	*Blue*	*Blue*
Presentation	*Non-Sterile*	*Non-Sterile*

VI. Performance Date

The device is manufactured in compliance with Quality System meeting the requirements of the Food and Drug Administration's Quality System Regulations (21 CFR 820), DIN EN ISO13485:2003 and / or DIN EN ISO 9001:2000. The device is manufactured to comply with recognized consensus and safety standards listed below:

- EN 61000-6-1 Electromagnetic compatibility (EMC) – Part 6-1: Generic standards – Immunity standard for residential, commercial and light-industrial environments

- EN61000-6-3 Electromagnetic compatibility (EMC) – Part 6-3: Generic standards – Emission standard for residential, commercial and light-industrial environments

Conclusion

Pursuant to the testing and comparison to the predicate device, the Absolute White Light has the same intended use, with similar function and performance characteristics. Therefore, the Company believes that the Absolute White Light is substantially equivalent to currently marketed devices, such as the Dentovations Luster Whitening System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Fresh, Incorporated
C/O Ms. Joyce Heinrich
Regulatory Consultant
Texas Applied Biomedical Services
12101 Cullen Boulevard
Houston, Texas 77047-1131

JAN 1 2 2012

Re: K110888
Trade/Device Name: Absolute White Light
Regulation Number: 21 CFR 872.6475
Regulation Name: Heat Source for Bleaching Teeth
Regulatory Class: I
Product Code: EEG
Dated: December 20, 2011
Received: January 5, 2012

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT I

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110888

Device Name:

Absolute White Light

Indications for Use:

The Absolute White Light emits visible blue light in the 400 nanometer spectrum and is intended to provide a light source for bleaching teeth.

Prescription Use: _____ **AND/OR Over the Counter Use:** X
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODPE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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